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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/546,573	04/10/00	HOLTEN-ANDERSEN	M 19829-000300

020350 HM12/0405  
TOWNSEND AND TOWNSEND AND CREW  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO CA 94111-3834

EXAMINER

RAWLINGS, S  
ART UNIT PAPER NUMBER

1642  
DATE MAILED:

04/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

**Office Action Summary**

Application No.

09/546,573

Applicant(s)

HOLTEN-ANDERSEN ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-37 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Restriction Election facsimile sheet*.

### DETAILED ACTION

1. Claims 1-37 are pending in the application and are currently subject to restriction.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

#### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Denmark on April 9, 1999. It is noted, however, that applicant has not filed a certified copy of the 1999 00476 application as required by 35 U.S.C. 119(b).

#### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-5, 13-19, 27, and 30-37, drawn to a method for determining whether an individual is likely to have cancer comprising determining the concentration of TIMP-1 in body fluid samples, classified in class 435, subclass 7.23 or class 204, subclass 450.

Group II. Claims 6-14, 20-27, and 30-37, drawn to a method for determining whether an individual is likely to have cancer comprising determining at least one second parameter in addition to the concentration of TIMP-1 in body fluid samples, classified in class 435, subclass 7.23 and/or class 204, subclass 450.

Group III. Claims 1-5, 13, 14, and 28-37, in so far as the claims are drawn to a method for detecting early stage cancer comprising determining the

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concentration of TIMP-1 in body fluid samples, classified in class 435, subclass 7.23 or class 204, subclass 450.

Group IV. Claims 6-14 and 28-37, in so far as the claims are drawn to a method for detecting early stage cancer comprising determining at least one second parameter in addition to the concentration of TIMP-1 in body fluid samples, classified in class 435, subclass 7.23 and/or class 204, subclass 450.

4. The inventions are distinct, each from the other because of the following reasons:  
Inventions I-IV are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

More specifically, the specification teaches in Figure 17 that the inventions of Groups 1/3 and 2/4 differ significantly in diagnostic sensitivity (see page 30, lines 6-28) and accordingly one method will have a criteria for success that is distinct from the other. Furthermore, the objectives of practicing the inventions in Groups 1/2 and 3/4, as disclosed, are different. Therefore, the methods in groups I-IV are distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. A telephone call was made to Kevin Bastian on March 26, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


**Conclusion**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Art Unit 1642

  
DONNA WORTMAN  
PRIMARY EXAMINER

slr

March 26, 2001



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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